Title 16. Board of Pharmacy
Second Modified Text

Changes made to the originally proposed language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Changes made to the first modified language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Inventory Reconciliation Report of Controlled Substances

a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.
b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.
c) A pharmacy or clinic shall compile an ~~I~~inventory ~~R~~reconciliation ~~R~~report of all federal Schedule II controlled substances at least every three months. This compilation shall require:
    1) A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;
    2) A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last ~~I~~inventory ~~R~~reconciliation ~~R~~report;
    3) A comparison of (1) and (2) to determine if there are any variances; ~~and~~
    4) All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form~~.~~; and
    5) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.
d) A pharmacy or clinic shall report in writing identified ~~L~~losses and known ~~possible~~ causes~~,~~ ~~shall be identified in writing and reported~~ to the board ~~and, when appropriate, to the Drug Enforcement Administration~~ within 30 days unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions ~~security improvements~~ necessary to prevent additional losses of controlled substances.

~~e)~~ ~~Likely Possible causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report.~~

e) ~~f)~~ The Inventory Reconciliation Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or professional director~~,~~ (if a clinic~~,~~) and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.

f) ~~g)~~ A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report ~~within 30 days of becoming pharmacist-in-charge~~ as identified in subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report as required in subdivision (c).

g) ~~h)~~ For inpatient hospital pharmacies, a separate quarterly ~~I~~inventory ~~R~~reconciliation ~~R~~ report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.

h) ~~i)~~ The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:

1) All controlled substances added to an automated drug delivery system are accounted for;
2) Access to automated drug delivery systems is limited to authorized facility personnel;
3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and
4) Confirmed losses of controlled substances are reported to the board~~,~~ ~~; and~~
5) ~~A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104, 4105.5, 4119.1, and 4332, Business and Professions Code and 1261.6, Health and Safety Code.